



DEPARTMENT OF HEALTH & HUMAN SERVICES

JUL 2 1999

Food and Drug Administration
Rockville MD 20857

6385 '99 JUL -6 A9:36

The Honorable Patsy T. Mink
House of Representatives
Washington, D.C. 20515-1102

Dear Ms. Mink:

Thank you for your letter dated May 18, 1999, concerning actions by the Food and Drug Administration (FDA or the Agency) in regard to labeling of foods treated with ionizing radiation.

The 1997 FDA Modernization Act (PL 105-115) states that "[n]o provision . . . shall be construed to require on the label or labeling of a food a separate radiation disclosure statement that is more prominent than the declaration of ingredients" FDA published a final rule implementing this provision of the law in the Federal Register of August 17, 1998. A copy of this regulation, along with the pre-existing labeling requirements for food treated with ionizing radiation (21 CFR 179), are enclosed for your information.

In addition, the Statement of Managers accompanying the FDA Modernization Act directed FDA to publish for public comment further proposed changes to the Agency's current labeling regulations. The managers stated their intention that any required labeling be of a type and character such that it would not be perceived to be a warning or give rise to inappropriate consumer anxiety. On February 17, 1999, FDA published an Advance Notice of Proposed Rulemaking (ANPR) in the Federal Register soliciting public comment on whether additional revisions to the current irradiation labeling requirements are needed and, if so, what form such revisions might take. The deadline for comments in response to the ANPR has been extended to July 19, 1999.

We have forwarded your correspondence to the Docket for inclusion in the record. FDA's final approach to labeling of irradiated foods will take into account all of the data and information received.

98N-1038

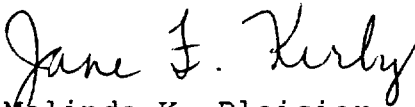
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In regard to irradiation labeling for meat and poultry, you may also wish to contact the United States Department of Agriculture (USDA) for information. (USDA has primary regulatory authority over meat and poultry products, including the labeling of such products.)

We have also enclosed some general background on the issue of irradiation. We trust this responds to your concerns. If we may be of further assistance, please contact us again.

Sincerely,


for Melinda K. Plaisier
Interim Associate Commissioner
for Legislative Affairs

Enclosures

cc: Dockets Management Branch
(98N-1038)

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SECOND DISTRICT, HAWAII

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JANE E. HENNEY, M.D.
COMMISSIONER
FOOD AND DRUG ADMINISTRATION
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5630 FISHERS LANE
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ROCKVILLE MD 20857

Dear Dr. Henney:

RE: Docket No. 98N-1038
Irradiation in the Production, Processing, and Handling of Food

I am writing to express my concerns about the the proposed revisions of the FDA's labeling requirements for foods treated with ionizing radiation.

I agree with the roundtable participants that irradiated foods should continue to be labeled and that the language should be provided in an informative, truthful and a non-threatening way.

Despite the lack of scientific research proving ill health effects caused by irradiation, many people continue to be suspicious of irradiation and wish to avoid consuming irradiated foods. For this reason I believe that any policy dealing with the subject of labeling of irradiated foods should err on the side of providing the consumer more information rather than less. Therefore, the answer to question 6 in the request for comments, is that consumers *would* be mislead by the absence of a radiation disclosure statement.

With respect to question 3 concerning whether the irradiation disclosure statement causes "inappropriate anxiety," I believe the public should be educated on the subject of irradiation and given the opportunity to decide for themselves if such anxiety is "inappropriate" or in fact warranted.

As many still believe the long term effects of consuming irradiated foods is unknown, consumers should be provided to opportunity to decide for themselves if they are to consume foods that have undergone such treatment.

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No. 99-3357

J.K.

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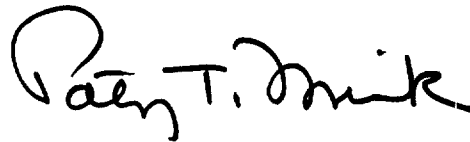
Jane E. Henney, M.D.

May 18, 1999

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Thank you for your consideration.

Very truly yours,

A handwritten signature in black ink, reading "Patsy T. Mink". The signature is fluid and cursive, with the first name "Patsy" being more prominent and the last name "Mink" following in a similar style.

PATSY T. MINK
Member of Congress